



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,352	12/11/2003	Matt D. Pursley	PUR-020	3757
26821	7590	07/05/2005	EXAMINER	
THOMPSON & THOMPSON, P.A. P.O BOX 166 SCANDIA, KS 66966			BECK, DAVID THOMAS	
		ART UNIT		PAPER NUMBER
		1732		

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,352	PURSLEY, MATT D.	
	Examiner David T. Beck	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 April 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,3,5,6,28,29,31,32,36,37,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2,3,5,6,28,29,31,32,36,37,50 and 51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 April 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Drawings

1. The drawings were received on 4/25/05. These drawings are accepted.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 3, 5, 6, 24, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Klint (2001/0044633) and Pursley (6,030,371).

With regard to claim 28, Sarge et al teaches a method of making a catheter (abstract), comprising the steps of: winding a filament onto a core member while rotating the core member relative to a filament source and passing the filament source in a first direction of axial movement relative to the core member, and reversing a direction of axial movement of the filament source while continuing to wind the filament onto the core member, whereby the filament is continuously wound onto the core member to form a first fibrous layer as the filament source is moved relative to the core member from a first axial position to a second axial position and then back to the first axial position (paragraph 0067). Klint teaches winding a group of filaments simultaneously (paragraph 0015). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to wind a group of filaments

simultaneously in the process taught by Sarge et al. The motivation to do so would have been to promote the uniform and well-defined characteristics along the length of the catheter (Klint, paragraph 0065). Pursley teaches providing a guide assembly having a filament engaging surface, and arranging said guide assembly such that the filament engaging surface lies in a plane which is generally perpendicular to a longitudinal axis of the core member (Figure 1b). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use the guide assembly taught by Pursley in the process taught by Sarge et al. The motivation to do so would have been to achieve a winding angle range that is far superior to the range achieved by other braiding/wrapping operations (Pursley, column 5, lines 45-51).

With regard to claim 2, Sarge et al teaches anchoring the filament at or near a proximal end of the core member before winding the filament onto the core member (paragraph 0063).

With regard to claim 3, Sarge et al teaches the filament is wound onto the core member continuously from the proximal end of the core member to a distal end thereof and then back to the proximal end (paragraph 0065-0067; Figure 3).

With regard to claim 5, Sarge et al teaches that the core member is a mandrel on which the catheter is formed (paragraph 0080).

With regard to claim 6, Sarge et al teaches that the core member is a substrate that forms an inner lining of the catheter (paragraph 0063).

With regard to claim 24, Klint teaches that the group of filaments is wound with a variable pitch such that a filament group spacing at a distal end of the core member is

narrower than a filament group spacing at a proximal end of the core member (paragraph 0020, reducing the number of wires changes the spacing).

4. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Clint (2001/0044633), Pursley (6,030,371) and McMickle et al (4,484,586).

With regard to claim 29, Sarge et al in view of Clint and Pursley teaches the invention of claim 28, and teaches varying a pitch of the group of filaments being wound onto the core member (Sarge et al, paragraph 0067), but does not explicitly teach varying a rotation speed of the core member or a translation speed of the filament source along the core member. McMickle teaches varying the pitch by changing the rotation speed in relation to the translation speed (column 2, lines 45-47). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to vary the pitch in the process taught by Sarge et al by changing the rotation speed in relation to the translation speed. The motivation to do so would have been to form a length of tubing with varying degrees of flexibility along its length (McMickle et al, column 2, lines 47-50).

5. Claims 32, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clint (2001/0044633) in view of Sarge et al (2001/0041881) and Pursley (6,030,371).

With regard to claim 36, Clint teaches a method of making a catheter (abstract), comprising the step of winding a group of filaments simultaneously onto a core member (paragraph 0015) but does not expressly teach rotating the core member relative to a

source of said filaments and passing the source of filaments in a first direction of axial movement relative to the core member. Sarge et al teaches rotating the core member relative to a source of said filaments and passing the source of filaments in a first direction of axial movement relative to the core member (paragraph 0067). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to wind the filaments in the process taught by Clint by rotating the core member and passing the filaments in a first direction as taught by Sarge et al. The motivation to do so would have been to wind the filaments at different pitches (Sarge et al, paragraph 0066). Pursley teaches providing a guide assembly having a filament engaging surface, and arranging said guide assembly such that the filament engaging surface lies in a plane which is generally perpendicular to a longitudinal axis of the core member (Figure 1b). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use the guide assembly taught by Pursley in the process taught by Clint. The motivation to do so would have been to achieve a winding angle range that is far superior to the range achieved by other braiding/wrapping operations (Pursley, column 5, lines 45-51).

With regard to claim 32, Clint teaches that the group of filaments is wound with a variable pitch such that a filament group spacing at a distal end of the core member is narrower than a filament group spacing at a proximal end of the core member (paragraph 0050).

With regard to claim 37, Sarge et al teaches reversing a direction of axial movement of the source of filaments relative to the core member while continuing to

Art Unit: 1732

wind the group of filaments onto the core member, whereby the filaments are continuously wound onto the core member as the source of filaments is moved relative to the core member from a first axial position to a second axial position and then back to the first axial position (paragraph 0068). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to move source of filaments relative to the core member from a first axial position to a second axial position and then back to the first axial position. The motivation to do so would have been to form two layers of filaments to build a catheter having two or more discrete tubular members having different performance characteristics (Sarge et al, paragraph 0011).

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klint (2001/0044633) in view of Sarge et al (2001/0041881), Pursley (6,030,371) and McMickle et al (4,484,586).

With regard to claim 31, Klint in view of Sarge et al and Pursley teaches the invention of claim 36, and teaches varying a pitch of the group of filaments being wound onto the core member (Klint, paragraph 0020), but does not explicitly teach varying a rotation speed of the core member or a translation speed of the filament source along the core member. McMickle teaches varying the pitch by changing the rotation speed in relation to the translation speed (column 2, lines 45-47). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to vary the pitch in the process taught by Klint by changing the rotation speed in relation to the translation speed. The motivation to do so would have been to form a length of tubing with varying degrees of flexibility along its length (McMickle et al, column 2, lines 47-50).

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Klint (2001/0044633).

With regard to claim 50, Sarge et al teaches a method of making a catheter (abstract), comprising the steps of: winding a filament onto a core member while rotating the core member relative to a filament source and passing the filament source in a first direction of axial movement relative to the core member, and reversing a direction of axial movement of the filament source while continuing to wind the filament onto the core member, whereby the filament is continuously wound onto the core member to form a first fibrous layer as the filament source is moved relative to the core member from a first axial position to a second axial position and then back to the first axial position (paragraph 0067) and anchoring the filament at or near a proximal end of the core member before winding the filament onto the core member (paragraph 0063). Klint teaches winding a group of filaments simultaneously (paragraph 0015). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to wind a group of filaments simultaneously in the process taught by Sarge et al. The motivation to do so would have been to promote the uniform and well-defined characteristics along the length of the catheter (Klint, paragraph 0065).

8. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sarge et al (2001/0041881) in view of Klint (2001/0044633) and Pursley (6,030,371).

With regard to claim 51, Sarge et al in view of Klint teaches the invention of claim 50. Furthermore, Klint teaches orienting the group of filaments into a plane which is generally perpendicular to the longitudinal axis of the core member (Figure 7) and

causing the filaments to be naturally reoriented and packed tightly against one another (Figure 7). Pursley teaches providing a guide assembly having a filament engaging surface, and arranging said guide assembly such that the filament engaging surface lies in a plane which is generally perpendicular to a longitudinal axis of the core member (Figure 1b). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use the guide assembly taught by Pursley in the process taught by Sarge et al. The motivation to do so would have been to achieve a winding angle range that is far superior to the range achieved by other braiding/wrapping operations (Pursley, column 5, lines 45-51).

Response to Arguments

9. Applicant's arguments with respect to claims 28 and 36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1732

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Beck whose telephone number is 571-272-2942. The examiner can normally be reached on Monday - Friday, 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 517-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DTB
June 23, 2005

DTB



MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER